DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 24, 2011 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 16, 17, 20, 22-24 and 64 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to the rejection mailed July 22, 2010, applicant has amended the claims to specify that the glycolipid intermediary metabolite is a monosaccharide ceramide, which was and is still currently required in instant claim 16. Applicant continues to argue that the claimed invention is enabled for various reasons, all of which have previously been presented and properly addressed by the Office.

Applicant summarizes the discussion in the instant disclosure and Figures, which indicate that Gaucher's patients with HCV have increased HCV-specific T cells, HCV-specific IFNγ-

producing cells, increased HV-specific IL-10 producing cells, increased IFNγ serum levels, increased IL-4 serum levels and increased peripheral NKT lymphocytes when compared to HCV-infected patients without Gaucher's disease. Applicant concludes that Gaucher's patients with HCV have a more effective immune reaction to HCV than patients with HCV alone.

Applicant's summary of the data provided in the instant disclosure has been reviewed, but is found unpersuasive. The instant claims are drawn to a method of treating any cancer, viral infection (HCV is the elected viral infection) or autoimmune disease by administering an effective amount of an intermediary metabolite, monosaccharide ceramide. While the immune responses elicited by patients simultaneously infected with Gaucher's disease and HCV are encouraging, there is no indication or evidence that remotely suggests that increased quantities of any glycolipid monosaccharide ceramide leads to treatment of HCV. In fact, it is noted that patients suffering from Gaucher's disease and who become infected with HCV remain infected with HCV, with no indication that the acquired infection is ameliorated or even treated by the pre-existence of Gaucher's disease. Indication of HCV treatment as a result of the specific monosaccharide ceramide administered would include data showing decreased HCV-RNA titers and/or decreased incidence of liver inflammation or scarring. However, there is no data presented in the instant disclosure or in the prior art literature. Therefore, expanded guidance is required to enable the skilled artisan to use the invention as claimed.

Applicant asserts that the skilled artisan would understand that having Gaucher's disease is therapeutically equivalent to an HCV-infected patient being treated with a glucosylcerebroside (a monosaccharide ceramide), which would lead to the same beneficial immune parameters against HCV infection as is seen in the Gaucher's plus HCV-infected patients.

Applicant's assertion has been fully considered, but is found unpersuasive. There is no indication or data to support the conclusion that administration of a glucosylcerebroside (a monosaccharide ceramide) to an HCV-infected patient would result in a patient with sufficient beneficial immune parameters to treat the HCV infection, as asserted by the instant claims. It is noted on pages 2-3 of the instant disclosure that patients suffering from untreated Gaucher's disease (who supposedly have a build-up of glucosylcerebroside), also suffer from hepatomegaly, a symptom common to HCV infection. Therefore, it would be unpredictable to the skilled artisan whether the presence of hepatomegaly in the HCV-infected patient treated with a glucosylcerebroside is attributable to the HCV infection or the accumulation of the glucosylcerebroside. Therefore, the skilled artisan would be unable to determine whether HCV infection is ameliorated (treated) by the administration of a glucosylcerebroside or not. Would the HCV-infected patient administered a glucosylcerebroside in sufficient quantities to elicit the "beneficial immune parameters" discussed by applicant also be required to take alglucerase to reduce other pathologies associated with glucosylcerebroside build-up in Gaucher's disease?

In addition, patients suffering from Gaucher's disease that are also infected with HCV are encompassed within the scope of patients treated by the instant method claims. The instant claims assert that HCV infection is treated in any mammalian subject by the administration of any mammalian monosaccharide ceramide. However, since the HCV-infected patients already suffering from Gaucher's disease have an overabundance of glycosylcerebrosides in their systems, the skilled artisan would only predict that the presence of additional monosaccharide ceramides administered by the instant method would only exacerbate the Gaucher's disease. The skilled artisan would not be able to predict whether the additional monosaccharide ceramides

would further produce enhanced immune response parameters against the acquired HCV infection.

Applicant iterates that a review of the instant disclosure indicating immune parameters modulated by excess glucosylcerebroside experienced in HCV-infected patients with Gaucher's disease. Applicant summarizes the immune system parameters.

Applicant's assertion has been fully considered, but is found unpersuasive. Again, there is no indication or data to support the conclusion that administration of a glucosylcerebroside (a monosaccharide ceramide) to an HCV-infected patient would result in a patient with sufficient beneficial immune parameters to treat the HCV infection, as asserted by the instant claims.

Applicant states that monosaccharide ceramides are all very similar compounds that are known to have similar biological effects. Applicant asserts that treatment of an HCV-infected patient with any mammalian monosaccharide ceramide would likely lead to the beneficial immune profile exhibited by HCV-infected Gaucher's patients.

Applicant's arguments have been fully considered, but are found unpersuasive. There is no indication in the instant disclosure or in the prior art that supports applicant's assertion that any monosaccharide ceramide derived from any mammal are all similar in structure and function. The skilled artisan would be unable to readily identify a monosaccharide ceramide that would result in a beneficial immune profile sufficient in any and all HCV-infected patients to treat HCV infection, as asserted by the instant claims.

Applicant states that the only parameter of the claimed invention that is not specifically provided is the dose of the mammalian monosaccharide ceramide that would lead to the favorable immune profile described. Applicant opines that the skilled artisan would understand

that the dose of mammalian monosaccharide ceramides administered would lead to equivalent levels experienced by a Gaucher patient, resulting in an effective treatment.

Applicant's statements have been fully considered, but are found unpersuasive. Again, there is no indication or data to support the conclusion that administration of a glucosylcerebroside (a monosaccharide ceramide) to an HCV-infected patient would result in a patient with sufficient beneficial immune parameters to treat the HCV infection, as asserted by the instant claims. In addition, the skilled artisan would be unable to predict whether the presence of additional monosaccharide ceramides administered to a patient already suffering from Gaucher's disease by the instant method would do. The skilled artisan would not be able to predict whether the additional monosaccharide ceramides would further produce enhanced immune response parameters against the acquired HCV infection in a Gaucher's patient.

For at least these reasons, it is maintained that an undue quantity of experimentation would be required of the skilled artisan to use the invention.

Conclusion

This is a continuation of applicant's earlier Application No. 10/733489. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is (571)272-0898. The examiner can normally be reached on flex, generally M-F 7AM - 3 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on (571) 272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SHANON A. FOLEY/
Primary Examiner
Art Unit 1648